K001100

MAY - 5 2000

2 Summary and Certification

2.1 Premarket Notification 510(k) Summary

SUBSTANCIAL EQUIVALENCE:
Identification of predicate devices, models, and manufacturers:

Predicate electrode device:	CardioDynamics Dual Snap Bioimpedance Sensor within BioZ.com System
Model:	Part # BZ-200
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K974725
Reason for Submission:	Modifications to electrode shape, foam thickness, snap size, and gel type

Predicate cable device:	CardioDynamics External Patient Cable within BioZ.com System
Model:	Part # BZ-4503-01
Manufacturer:	CardioDynamics International Corporation
Predicate Device 510(k):	K974725
Reason for Submission:	Modifications to conductor number and leadwire connectors

The BioZ.com Hemodynamic Monitor with BioZ Tect Sensor and BioZ Tect Cable is substantially equivalent to its predicate device, the BioZ.com System currently marketed by CardioDynamics International Corporation. The justification for this substantial equivalence determination is presented below.

The BioZ.com Hemodynamic Monitor with BioZ Tect Sensor and BioZ Tect Cable is substantially equivalent to the BioZ.com System in terms of design, intended use and principle of operation. The BioZ.com Hemodynamic Monitor with BioZ Tect Sensor and BioZ Tect Cable simply contains minimally modified electrode and patient cable accessories. Both systems are portable in design and for use in the hospital, outpatient and clinical settings. The intended use of the BioZ.com is to noninvasively measure a patient's hemodynamic parameters using thoracic electrical bioimpedance (TEB). Monitoring is accomplished by attaching 8 electrodes to the patient (two on each side of the neck and thorax), injecting a minimal current through the upper electrodes, and reading the returning voltage waveform from the inner electrodes.

The BioZ.com Hemodynamic Monitor utilizes CardioDynamics' proprietary DSP electronic circuitry and software incorporating formulas and algorithms to calculate the various hemodynamic parameters. The user inputs patient parameters into the BioZ.com, including patient gender, body frame size, height, weight, age and blood pressure. The

Monitor then utilizes these parameters and measures the TEB signals to determine the hemodynamic properties of that particular patient.

Both the predicate BioZ.com System and the BioZ.com Hemodynamic Monitor with BioZ Tect Sensor and BioZ Tect Cable use the BioZ.com, which is a self-contained, computer-based product. Each system contains the following:

1. BioZ.com Hemodynamic Monitor instrument containing
   A. CardioDynamics' proprietary DSP and Patient Interface Circuitry
   B. Intel 80386EX Processor Board
   C. CardioDynamics proprietary DSP firmware and user software
   D. Medical grade universal input power supply
   E. Built-in flat panel display
   F. Keyboard/keypad
   G. Power cord
2. BioZ Tect Sensors
3. BioZ Tect Cable Patient Cable

2.2 Truth and Accuracy Certification

PREMARKET NOTIFICATION
TRUTH AND ACCURACY STATEMENT
[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Technology Officer of CardioDynamics International Corporation, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Dennis G. Hepp
(Typed Name)

_____
(Dated)

_____
*(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2000

Mr. Dennis G. Hepp
Chief Technology Officer
CardioDynamics International Corporation
6175 Nancy Ridge Drive
San Diego, CA 92121

Re: K001100
Trade Name: BioZ.com Hemodynamic Monitor with BioZ Tect Sensor
BioZ Tect Cable
Regulatory Class: II
Product Code: DSB
Dated: February 29, 2000
Received: April 5, 2000

Dear Mr. Hepp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001100

Device Name: BioZ.com Hemodynamic Monitor with BioZ Tect Sensor and BioZ Tect Cable

Indications for Use: The BioZ.com Hemodynamic Monitor with BioZ Tect Sensor and BioZ Tect Cable is intended to monitor and display a patient's hemodynamic parameters. These parameters include:

ECG	Pre-Ejection Period	Systolic Time Ratio
Cardiac Output	Systemic Vascular Resistance	End diastolic Index
Thoracic Fluid Content	Acceleration Index	Heart Rate
Left Vent. Ejection Time	Stroke Volume	Cardiac Index
End Diastolic Volume	Index of Contractility	Respiration Rate
Left Cardiac Work		

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(PER 21 CFR 801.109)

(Optional Format 1-2-96)

Brian E. Hanover for J. E. Dillard III

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001100